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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,740	07/16/2003	Samuel Shiber	CT23	8980
30608	7590	12/12/2005	EXAMINER	
SAMUEL SHIBER 365 KEARNEY CR MANCHESTER, NH 03104			APANIUS, MICHAEL	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TJK

Office Action Summary	Application No.	Applicant(s)
	10/620,740	SHIBER, SAMUEL
	Examiner	Art Unit
	Michael Apanius	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) 14 and 15 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 16 July 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09082003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: at paragraph 31, line 2, "wire 35".
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: in figure 1, "16"; in figure 4, "32'".
3. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:
 - a. At paragraph 5, line 5, "through which" should be --and--.
 - b. At paragraph 7, line 2, "the a" should be --a--.
 - c. At paragraph 9, line 4, "ontains" should be --contains--.
 - d. At paragraph 22, line 9, "seal of the introducer 75" should be -- seal 75 of the introducer 20--.
 - e. At paragraph 27, line 11, --of-- should be inserted between "separation" and "the".
 - f. At paragraph 49, line 5, "rotating the while" is missing word(s).

Appropriate correction is required.

Claim Objections

5. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).
6. Misnumbered claims 15 and 16 been renumbered 14 and 15, respectively.
7. Claims 1-15 are objected to because of the following informalities:
 - g. At claim 1, the layout of the claim (using indentations and new lines) should be changed to clearly show that the thin elongated midsection (line 10)

and the proximal tubular coupling (line 14) are elements of the flexible casing (line 6). It is clear that the tubular distal portion (line 6) is part of the flexible casing but the indentations suggest that the thin elongated midsection and the proximal tubular coupling are elements of the entire system, rather than elements of the casing and the system.

- h. At claim 4, line 1, the "a" between "said" and "midsection" should be deleted.
- i. At claim 12, line 18, "a tubular coupling" should be --the tubular coupling--.
- j. At claim 12, line 19, the colon should be a semicolon.
- k. At claim 14, line 10, the line should be indented.
- l. At claim 14, line 17, "a tubular coupling" should be --the tubular coupling--.
- m. At claim 14, line 26 (last line of page 18), the line should end in with a semicolon.
- n. At claim 14, line 27 (first line of page 19), a semicolon should be inserted between "obstruction" and "and".
- o. At claim 15, line 6, the colon should be a semicolon.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. At claim 10, line 1 and claim 11, line 1, it is not clear if the "sleeve" recited is the same sleeve as that recited in claim 9, line 1.

11. At claim 12, line 21, "until its is past" renders the claim indefinite because the meaning of the statement is unclear.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinrib (US 4,706,671).

14. In regards to claim 1, Weinrib discloses a flexible guidewire system with an exposed midsection, for crossing an obstruction located in a patient's vessel, comprising in combination: a flexible pilot wire (41); a flexible casing having a tubular distal portion (42) made of a helical wire that is gated at its distal end, said distal portion being slidable and rotatable over said pilot wire; a thin elongated midsection (located at 20 in figure 3) connected to said distal portion, said midsection disposed alongside said pilot wire and is slidable along and rotatable around said pilot wire; and a proximal tubular

coupling (13) for rotating and linearly moving said casing over said pilot wire, said coupling being slidable and rotatable over said pilot wire and being connected to said midsection, wherein a section of said pilot wire that is disposed alongside said midsection of said casing is exposed.

15. In regards to claim 3, the casing is gated by closely wound coils of said helical wire (see distal portion of 42 in figure 3).

16. In regards to claim 4, the midsection of the casing is made of substantially straight wire that is a continuation of the helical wire.

17. In regards to claim 5, the distal portion of the casing is curved (the rotations of the helical wire).

18. Claims 1, 2 and 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiber (US 5,135,531).

19. In regards to claim 1, Shiber discloses a flexible guidewire system (figure 2) with an exposed midsection, for crossing an obstruction located in a patient's vessel, comprising in combination: a flexible pilot wire (160); a flexible casing having a tubular distal portion (170) made of a helical wire that is gated at its distal end, said distal portion being slidable and rotatable over said pilot wire; a thin elongated midsection (the lowermost quarter turn of element 170 as shown in figure 2) connected to said distal portion, said midsection disposed alongside said pilot wire and is slidable along and rotatable around said pilot wire; and a proximal tubular coupling (17) for rotating and linearly moving said casing over said pilot wire, said coupling being slidable and

rotatable over said pilot wire and being connected to said midsection, wherein a section of said pilot wire that is disposed alongside said midsection of said casing is exposed.

Note that the lowermost quarter turn of element 170 does not go entirely around the pilot wire and therefore is disposed alongside the pilot wire. Furthermore, the pilot wire is exposed because the turns of element 170 have space in between the turns.

20. In regards to claim 2, the distal end of the casing is gated by a tube section that is attached to the helical wire (see figure 7).

21. In regards to claim 5, the distal portion of the casing is curved (the rotations of the helical wire).

22. In regards to claim 6, the pilot wire is a standard guidewire (column 4, line 64).

23. In regards to claim 7, Shiber discloses an alternate pilot wire (figure 5, element 14) that is a hollow tube (column 5, lines 48-52).

24. In regards to claim 8, the alternate pilot wire has an inflatable chamber (15) attached to its distal end section.

25. In regards to claim 9, the guidewire system is disposed in a sleeve (figure 20, element 82; column 8, 45-54) with a biasing means to deflect the position of the casing in the vessel.

26. In regards to claim 10, the biasing means comprises a sleeve with a curved distal end section. The biasing means is curved when the inflatable chamber (81) is inflated.

27. In regards to claim 11, the biasing means comprises a sleeve with a selectively inflatable chamber (81) located at said distal end of said sleeve.

Allowable Subject Matter

28. Claims 12 and 13 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
29. Claims 14 and 15 would be allowable if rewritten or amended to overcome the objections set forth in this Office action.
30. The following is a statement of reasons for the indication of allowable subject matter: no prior art of record teaches or fairly suggests the method of crossing an obstruction in a patient's vessel using a flexible guidewire system as set forth in claims 12-15.

Conclusion

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,653,496 and US 4,935,025 discloses a transluminal lysing system. US 4,909,781 discloses a catheter with flexible cutter. US 6,740,096 discloses a treatment and removal of objects in anatomical lumens.
32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.
33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA



CHARLES MARMOR
PRIMARY EXAMINER